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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/866,279	05/30/1997	SUSAN M. DYMECKI	234805	9567

7590 06/05/2002
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EXAMINER

BAKER, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 06/05/2002

33

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/866,279

Applicant(s)

DYMECKI, SUSAN M.

Examiner

Anne Baker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *detailed action*.

DETAILED ACTION

The amendment filed March 18, 2002 (Paper No. 32) has been entered. Claims 50 and 51 have been amended. Claims 52-65 have been newly added.

Claims 1-65 are pending in the instant application.

The following rejections are reiterated or newly applied and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

Continued Prosecution Application

The request filed on March 18, 2002 (Paper No. 32) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/866,279 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-60 and 62-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic mouse comprising an FLP recombinase transgene under the control of a tissue-specific promoter and a reporter gene under the control of a non-tissue-specific (ubiquitous) promoter, wherein the reporter gene comprises a disruption comprising two FLP-recognition sequences in direct repeat orientation, such that the reporter gene produces active product only when in the recombined form, does not reasonably provide enablement for transgenic mice having

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the wide variety of different combinations of FLP-recognition sequences and transgenes, as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification fails to provide an enabling disclosure for the full scope of the claims because the phenotype of a transgenic mouse is unpredictable for reasons of record advanced on pages 2-6 of the Office Action of Paper No. 22 (mailed 10/25/00) and on pages 2-8 of Paper No. 26 (mailed 7/18/01). Thus, the specification fails to teach how to use the full scope of the claimed transgenic mice. In the absence of disclosure of a transgene-dependent phenotypic alteration, one skilled in the art would not know how to use the claimed transgenic mice over the full scope. Thus, one skilled in the art would have been required to engage in undue experimentation in order to make and use the claimed transgenic mice over the full scope.

At page 5, paragraph 2 of the response, Applicants argue that the claims specify that recombination occurs *in a cell* expressing sufficient recombinase activity, not in every cell of the mouse and therefore the scope conceded by the Examiner is unduly narrow because the specification teaches how to detect recombination using other means than a reporter gene, and also teaches other uses for the FLP recombinase that would not require the specific combination of promoters mentioned by the Examiner. No support is offered for this assertion. However, the Examiner agrees that there are other means to detect recombination. This is not sufficient to overcome the enablement rejection, however, as the claims must be congruent with the asserted utility of the invention, which in the instant case is cell fate mapping. The specification does not teach how to use other means of recombination detection for cell fate mapping.

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Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic mouse comprising an FLP recombinase transgene under the control of a tissue-specific promoter, does not reasonably provide enablement for transgenic mice having the FLP recombinase transgene under the control of any type of promoter, as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

For the reasons incorporated and discussed above, the claims must be congruent with the asserted utility of the invention, which in the instant case is cell fate mapping.

Claims 54 and 61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly added Claims 54 and 61 recite the phrase “ubiquitous promoter.” Applicants have not pointed to any particular support in the specification for this element and the Examiner does not find literal support. Applicants have pointed to the first paragraph on page 37 as support for new Claim 54. However, there is no support for the term “ubiquitous promoter.” Thus, this constitutes new matter in the claims. If Applicants cannot point to specific support for the term “ubiquitous promoter,” use of the phrase “non-tissue specific promoter” is suggested, but only if Applicants can point to support.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-65 are indefinite in their recitation of a "Flp transgene" because it is unclear what the transgene actually encodes. Use of the phrase "Flp recombinase transgene" is suggested.

Claim 1 is indefinite in its recitation of "of the cell" because inclusion of this phrase makes it unclear as to whether or not the transgenic mouse comprises cells the comprise Flp-recognition sequences. It is suggested that this phrase be removed from the claim, so that it is clear that the "wherein" clause only requires a particular level of Flp recombinase expression, and does not necessarily require that any actual recombination takes place in the transgenic mouse. Claim 1 would be allowable if this phrase were deleted and "Flp transgene" was amended to "Flp recombinase transgene."

Claim 51 is indefinite in its recitation of "said genes controlling differentiation of a cell or development of an organism" because it is unclear whether Claim 51 is intended to be limited to "genes controlling differentiation of a cell or development of an organism," given that Claim 15 is not limited to "genes controlling differentiation of a cell or development of an organism." Therefore, Claim 51 still encompasses all the other genes recited in the Markush group of Claim 15, with only the further limitation that the "genes controlling differentiation of a cell or development of an organism" are now limited to the specific ones recited in the Markush group of Claim 51.

Claim 51 is indefinite in its recitation of "metabolic enzymes" and "growth/differentiation factors and their receptors" because the metes and bounds are not clearly set forth. The specification does not offer a definition of these terms that would define the metes and bounds.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Baker whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Anne-Marie Baker, Ph.D.


ANNE-MARIE BAKER
PATENT EXAMINER